

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

FILED

FEB 18 2011

UNITED STATES OF AMERICA, ex rel.)
ALAN KOZIKOWSKI, Relator;)

Plaintiffs,)

v.)

MICHAEL H. JOHNSON; JERRY L.)
BAUMAN; LARRY H. DANZIGER; and)
ERIC A. GISLASON;)

Defendants.)

MICHAEL W. DOBBINS
CLERK, U.S. DISTRICT COURT

11cv1161
JUDGE HOLDERMAN
MAG. JUDGE GILBERT

FILED UNDER SEAL

JURY TRIAL DEMANDED

COMPLAINT

Now comes the United States of America, on relation of Dr. Alan Kozikowski, and complains against Defendants Michael H. Johnson, Larry H. Danziger, Jerry L. Bauman, and Eric A. Gislason, as follows:

Nature of The Case

1. This is a *qui tam* action pursuant to the federal False Claims Act, 31 U.S.C. § 3729, *et. seq.* It seeks to recover damages and penalties for Defendants' false claims to federal agencies for grant awards. Defendants are professors and administrators at the University of Illinois – Chicago ("UIC").

2. Led by Defendant Johnson, Defendants have lied to federal agencies to obtain more than \$17 million for three grants. First, Defendants double-counted Dr. Johnson's work by allocating the same work to two separate grants: a \$15 million 2003-08 grant from the National Institutes of Health ("NIH") and a later \$880,000 grant from the Department of Defense ("DOD").

3. Second, Defendants obtained the \$15 million 2003-08 NIH grant using false pretenses. Defendants represented that a colleague from UIC, Dr. Richard van Breemen, would be a key researcher on a portion of the grant to which NIH expressly directed approximately \$1.4 million. In fact, Defendants never actually allocated any money to Dr. van Breemen. Third, Defendants committed the same type of fraud on a separate \$4 million grant, representing to NIH that about \$600,000 would be allocated to research to be performed by Dr. Kozikowski but then allocating only \$300,000 to that research once NIH funded the grant.

4. This action seeks to recover the damages suffered by the government as a result of these false claims, as well as the penalties mandated by the False Claims Act.

Parties

5. Relator Alan Kozikowski is a citizen of Illinois. He is a professor in UIC's Department of Medicinal Chemistry and Pharmacognosy and is the Director of UIC's Drug Discovery Program. Dr. Kozikowski is one of the world's leading medicinal chemists, holding more than 100 patents and having published more than 400 peer-reviewed articles.

6. Defendant Michael E. Johnson is a citizen of Illinois and a professor in UIC's Department of Medicinal Chemistry and Pharmacognosy.

7. Defendant Jerry L. Bauman is a citizen of Illinois. He is currently the dean of UIC's College of Pharmacy, which includes the Department of Medicinal Chemistry and Pharmacognosy.

8. Defendant Larry E. Danziger is a citizen of Illinois and since 2008 has been the Vice Chancellor for Research at UIC.

9. Defendant Eric A. Gislason is a citizen of Illinois and was the Vice Chancellor of Research at UIC immediately prior to Defendant Danziger.

Jurisdiction and Venue

10. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 because the case arises under a federal statute, 31 U.S.C. § 3729, *et seq.* There has been no public disclosure of the fraud alleged herein. Further, Dr. Kozikowski is an original source of the information in this Complaint because he has direct and independent knowledge of the fraud through his work at UIC and he voluntarily reported it to the government before filing suit.

11. Venue is proper because a substantial portion of the events giving rise to this action occurred in this judicial district.

Additional Facts

Dr. Kozikowski's Background

12. Dr. Kozikowski is one of the world's leading medicinal chemists. He received his Bachelor of Science from the University of Michigan in 1970, and his Ph.D. from the University of California at Berkeley in 1974. Dr. Kozikowski then engaged in postdoctoral work at Harvard University from 1974-76. After that, he joined the faculty of the University of Pittsburgh, where he taught and researched from 1976-90. From 1990-93, he was a professor and consultant at Mayo Clinic, and then from 1993-95 served as vice president of Trophix Pharmaceuticals. Dr.

Kozikowski then joined the faculty at Georgetown University Medical Center from 1995-2003.

13. In August 2003, Dr. Kozikowski accepted an offer from UIC to join its faculty as a fully tenured professor.

14. Dr. Kozikowski's work focuses on the discovery of new drugs. He has discovered innovative drug therapies for conditions ranging from Alzheimer's to toxoplasmosis. Dr. Kozikowski regularly serves on scientific review committees for NIH and foreign governments, and has frequently served as an expert on pharmaceutical patents in federal and state litigation.

Defendants' Misrepresentations

15. Dr. Johnson and the other Defendants made a series of misrepresentations to NIH and DOD that resulted in those agencies paying out grant money they otherwise would not have. In the main, the three frauds perpetrated by Defendants were (1) knowingly misrepresenting to the DOD in the application for the \$880,000 2007-08 grant that there was no overlap between the work Dr. Johnson was doing for the 2003-08 NIH grant and the work he proposed doing for the DOD, (2) eliminating the entire budget for Dr. van Breemen's work on the 2003-08 NIH grant and removing him from that grant, and (3) eliminating half of the budget NIH allocated to Dr. Kozikowski's work on a 2009-10 NIH grant.

2007-08 DOD grant application and work

16. On January 9, 2007, Defendants Johnson, Gislason, and Bauman submitted application W81XWH-BAA06-1 to the DOD ("DOD Grant"). The

application sought \$1 million to create the Institute for Advanced Pharmaceutical Sciences at UIC.

17. Defendants described the purpose of the Institute as follows: “Anthrax continues to be a major threat to our national security and economy. Because the potential for the bioterrorist use of anthrax remains high, and since drug resistant anthrax can be generated in the laboratory, the development of novel therapeutics remains urgent.” The main objective of the DOD Grant was “to develop molecular targets and drug screens as countermeasures to combat bioterrorism due to *B. anthracis* [commonly known as ‘anthrax’] and other infectious agents.”

18. The DOD Grant application proposed four projects and three administrative “cores” that would support all four projects. Defendant Johnson was designated as the principal investigator of the third project, which sought \$105,000 in direct costs and an additional unspecified amount for indirect costs. The aims of Dr. Johnson’s project were to:

- (1) choose the most effective current compound from our group of potential lead compounds, and to improve its dosing and delivery as an anthrax therapeutic antibiotic;
- (2) pursue further chemical improvement strategies to improve metabolic and pharmacokinetic (ADME) properties of current lead FabI inhibitors; and
- (3) test FabI inhibitors that show *in vivo* efficacy against *B. anthracis* for potential *in vitro* efficacy against *F. tularensis* and *Y. pestis*.

19. As part of the DOD Grant application, Defendant Johnson submitted a list of grant support he was already receiving at the time. For each grant, Defendant Johnson was required to state whether there was any overlap between

his current grant work and the work he was proposing to do for the DOD.

Defendant Johnson disclosed the 2003-08 NIH grant and answered whether there was any overlap with the proposed DOD work by stating: "OVERLAP: NONE."

20. On June 1, 2007, the DOD approved the DOD Grant application and awarded UIC the entire \$880,000 requested. In January 2009, Defendant Bauman issued the final report for the work done pursuant to the DOD Grant. The final report stated that the "principal reportable outcomes of this research are the six scientific papers and one abstract detailed below." Defendant Johnson co-authored two of these papers reported as outcomes of the DOD Grant: "Design and synthesis of aryl ether inhibitors of the *Bacillus anthracis* enoyl-ACP reductase" in *ChemMedChem* in 2008 and "Design and synthesis of 2-pyridones as novel inhibitors of the *Bacillus anthracis* enoyl-ACP reductase" published in *Bioorganic & Medicinal Chemistry Letters* in 2008.

21. Dr. Kozikowski was the lead author of both of these papers.

2003-08 NIH grant application and work

22. Despite promising the DOD that his work on the 2003-08 NIH grant did not overlap with his work on the DOD Grant, in fact all of the work that Defendant Johnson reported for the DOD Grant overlapped with his work on the 2003-08 NIH grant.

23. On November 22, 2002, Defendant Johnson signed grant application 1 U19A1056575-01 to NIH ("U19 Grant"). Defendant Gislason, who was then the

Vice Chancellor of Research for UIC, signed the grant application on behalf of UIC on November 25, 2002.

24. The U19 Grant application requested approximately \$19 million to fund research into combating “drug-resistant strains of *B. anthracis*.” The application described drug-resistant anthrax as “a substantial threat in future terrorist attacks.” The U19 Grant application proposed five different projects to combat drug-resistant anthrax, as well as five administrative cores to support those projects.

25. The proposed projects were: (1) develop antibiotic inhibitors to anthrax; (2) genetically identify the drug targets of anthrax; (3) design novel treatments for anthrax; (4) develop inhibitors for anthrax’s protective antigen, which is one of the mechanisms anthrax uses to defeat drugs; and (5) develop treatments for the anthrax shock syndrome.

26. On August 13, 2003, NIH agreed to fund the U19 Grant for five years for a total of \$15,727,528.

27. From 2003 to 2008, the U19 Grant consumed the bulk of Defendant Johnson’s working hours and attention. As principal investigator, Defendant Johnson oversaw the work of at least five other professors at UIC and dozens of research assistants. In addition to being the overall principal investigator of the grant, Defendant Johnson was the project leader for Project 3 and the core leader for Core A (administration of the grant).

Overlap in work on the two grants

28. Defendant Johnson's work on the U19 Grant overlapped with the work he claimed he would do on the DOD Grant.

29. The work that went into the only two papers that Defendant Johnson reported as outcomes of the DOD Grant was completed *before* the DOD Grant was issued. The final report for the DOD Grant identified both the *ChemMedChem* and *Bioorganic & Medicinal Chemistry Letters* ("BMCL") papers as among the "principal outcomes" of the DOD Grant. That claim is impossible.

30. The DOD Grant was issued in June 2007. The *ChemMedChem* paper was drafted by August 24, 2007, and it is impossible that any work from the DOD Grant was used to complete that draft.

31. Also, the initial drafts of that paper acknowledged only the U19 Grant as a source of funding, but Defendant Johnson later inserted a reference to the DOD Grant as a funding source.

32. Similarly, a first draft of the *BMCL* paper was completed before October 2007. Again, all of the research that went into the *BMCL* paper was supported by the U19 Grant and was completed well before the DOD Grant was funded in June 2007.

33. Also, like the *ChemMedChem* paper, the initial drafts of the *BMCL* paper did not acknowledge the DOD Grant as a funding source, and Defendant

Johnson's research staff insisted that the *BMCL* paper identify the DOD Grant as a funding source.

34. In other words, these two papers are the entire output that Defendant Johnson claimed for the DOD Grant, yet the work that went into them was paid for by the U19 Grant and was completed before the DOD Grant was issued.

Unilateral removal of Richard van Breemen from the U19 Grant

35. As discussed above, the U19 Grant proposed work on four projects, each to be supported by five administrative cores. One such core – Core E – was the screening of thousands of chemical compounds to determine which would be useful to the projects. The U19 Grant application identified UIC Professor Richard van Breemen as co-investigator of Core E.

36. Defendant Johnson requested \$1,452,220 in direct costs over five years for Core E, with the substantial majority of this funding to go toward obtaining equipment and supplies for Dr. van Breemen's lab and paying a post-doctoral researcher and a research technician.

37. The U19 Grant application was reviewed by a panel of scientists who recommended that NIH approve the award essentially unchanged (it approved the full amount of the request but recommend that the research technician position should not be filled until the second year of the grant and the equipment budget should be halved).

38. On August 13, 2003, NIH agreed to fund the U19 Grant for five years for a total of \$15,727,528. According to the internal UIC notice of grant award, NIH allocated \$149,544 to Core E in the initial grant period (a period of less than a full year), which is roughly equivalent to the amount recommended by the review panel.

39. Despite the assurances that Defendants Johnson and Gislason made about how the U19 Grant money would be spent, Defendant Johnson almost immediately set about diverting money from Core E. Defendant Johnson cut off Dr. van Breemen from the grant without ever informing Dr. van Breemen himself. He was never invited to any meetings once the money came in and Dr. Johnson never explained to him why he was removed from the grant.

*Unilateral halving of Relator's budget on 2009-10 NIH grant
without obtaining NIH approval*

40. On June 15, 2007, Defendants Johnson and Gislason submitted application U01AI077949 to NIH seeking \$12,307,853 for a five-year period. The application proposed that Dr. Johnson would oversee "develop[ment of] new therapeutic agents against" anthrax, tularemia, and the plague.

41. The application identified four aims for the project:

- a. develop inhibitors of the enzyme enoyl reductase, also known as "FabI." FabI are enzymes that help anthrax, tularemia, and the plague spread. The project was attempting to develop therapies that would both "turn off" these enzymes and attack the anthrax, tularemia, or plague bacteria itself.
- b. develop inhibitors of another enzyme known as "MenE" (full name: *o*-succinylbenzoyl-CoA synthetase). Like FabI, MenE is an enzyme that helps anthrax, tularemia, and plague spread. The project planned to

develop MenE inhibitors that also retained some antibiotic properties to attack the bacteria itself.

- c. chemically improve any MenE leads that the project developed.
- d. test the FabI and MenE leads on animals.

42. The application named Dr. Kozikowski a co-investigator; he was to oversee the medicinal chemistry aspects of the work. The initial U01 Grant application sought \$291,808 in direct cost for Dr. Kozikowski's work in the first year, with approximately 4 percent increases for each subsequent year.

43. Although NIH did not initially fund this grant application, in 2009 NIH requested that Defendant Johnson resubmit the U01 Grant application as a two-year project in the hopes that it would qualify for funding under the American Recovery and Reinvestment Act of 2009.

44. On June 29, 2009, Defendant Johnson submitted revised aims of the grant to NIH that accommodated the change from a five-year program to a two-year program. The aims of the project were reduced from four to three:

- a. discover alternate structural scaffolds for FabI inhibitors
- b. develop MenE inhibitors
- c. conduct initial *in vitro* toxicology testing on the best candidates

45. These aims were essentially the same as in the original application. The only difference is the elimination of chemical improvement of MenE leads as a stand-alone aim, and this revision did not affect Dr. Kozikowski's work.

46. On August 19, 2009, Defendants Johnson and Danziger submitted a revised budget proposal to NIH that adjusted the budgets to reflect the revised aims

communicated by Defendant Johnson on June 29, 2009. The revised application sought \$4,072,758 in total.

47. The August 19, 2009 revised budget proposal identified the “General budget modifications to accommodate reduction to two-year ARRA funding related to revisions in specific aims.” The brief description notes that funds that had been allocated to George Mason University and Protez Pharmaceuticals were eliminated from the proposed budget.

48. Critically, the requested budget for Relator’s work remained *almost exactly the same* as in the original grant application: \$291,009 in direct costs the first and second years.

49. Dr. Johnson and UIC submitted no further revised budgets to NIH after that.

50. On September 17, 2009, NIH approved the U01 Grant application and awarded UIC \$4,020,530, nearly the exact amount requested in the revised application.

51. On September 29, 2009, Defendant Johnson informed Dr. Kozikowski in a meeting that the \$291,009 per year dedicated to Dr. Kozikowski’s work would be slashed by about half and that this money would be redirected to Defendant Johnson’s work. Defendant Johnson told Dr. Kozikowski that he had discussed this budget reduction with NIH personnel, when, in fact, Defendant Johnson never received approval from NIH for this budget reduction.

52. On November 3, 2009, Defendant Johnson removed Dr. Kozikowski entirely from the U01 Grant after Dr. Kozikowski refused to acquiesce to Defendant Johnson's attempts to remove Dr. Kozikowski's budget without NIH approval.

53. On November 12, 2009, Dr. Kozikowski e-mailed Rebecca Ann Lind, UIC's Assistant Vice Chancellor for Research, and informed her of his concern that his budget had been unilaterally removed from the U19 Grant by Dr. Johnson without NIH approval. On November 24, 2009, Dr. Lind responded to Dr. Kozikowski by memorandum stating:

According to UIC's Office of Research Services, the Specific Aims of the above-referenced grant were modified from those contained in the initial grant submission, given the two-year scope of ARRA funding, and responding to review panel recommendations. The subawards to George Mason University and Protez Pharmaceuticals were removed. These changes, described below, were communicated to and approved by the NIH.

54. Dr. Lind went on to repeat verbatim the three specific aims described in Dr. Johnson's August 19, 2009 e-mail submission to NIH. She concluded her memorandum to Dr. Kozikowski: "To accomplish the revised Specific Aims, subcontracts with George Mason University and Protez Pharmaceuticals were removed. The subcontract with Dr. David Case was changed from Scripps to Rutgers (his current institution)."

55. In other words, UIC's own Assistant Vice Chancellor for Research confirmed –after conducting a review within the Office for Research – that the *only* changes to the U19 Grant application that Defendant Johnson obtained approval for were the revised aims, none of which affected the work to be performed by Dr.

Kozikowski. Further, the *only* steps taken to facilitate these changes were the removal of two outside institutions and a change in affiliation for Dr. Case, which confirms that whatever changes Defendant Johnson obtained approval for were completely unrelated to Dr. Kozikowski or the research he was to do. Dr. Lind's November 24 memorandum is notably silent regarding any NIH approval for the slashing of funding for Dr. Kozikowski's work.

The False Claims

56. Through the above-described conduct, Defendants knowingly presented or caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729.

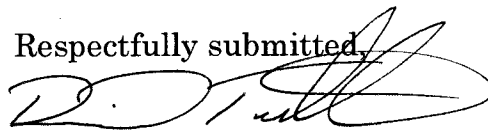
57. Through the above-described conduct, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get false or fraudulent claims paid or approved in violation of 31 U.S.C. § 3729.

Jury Trial Demanded

58. The United States of America, on relation of Dr. Kozikowski, hereby demands trial by jury on all issues so triable.

WHEREFORE, Relator Alan Kozikowski respectfully requests that the Court enter judgment in his favor and in favor of the United States of America against Defendants Michael E. Johnson, Jerry L. Bauman, Larry E. Danziger, and Eric A. Gislason, awarding treble damages and penalties for the False Claims Act violations and awarding Relator thirty percent of the government's recovery as well as his costs and attorneys fees incurred in this action.

Respectfully submitted,



Alan Kozikowski

By: One of Mr. Kozikowski's
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